

REMARKS

Applicant expresses gratitude to the examiner for withdrawing the rejection of claim 43 under 35 U.S.C. § 112, first paragraph, the rejection of claims 28-37, 39, and 41-43 under 35 U.S.C. § 112, second paragraph, and the rejections of claims 35-37 under 35 U.S.C. § 112, second paragraph.

By this amendment, claims 28 and 44 have been amended and claims 45-47 have been added. No new matter has been added.

Response to Rejections under 35 U.S.C. § 112

Claim 44 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the specification does not specifically teach lubricant film-forming combination **consisting of** at least one polyacrylic acid, at least one humectant, and water. Applicant respectfully disagrees and traverses the rejection.

Applicant submits that the specification provides written description support for claim 44 because it discloses that:

The **organic substances with a lubricant effect** may also be soluble, emulsifiable, dispersible, where appropriate low molecular weight, where appropriate biodegradable and/or where appropriate bioadhesive organic oligomers or polymers which can be formulated as **compositions which form lubricant films** or act as lubricants, for example with organic solvents, **water** or mixtures of solvents and water as vehicle.

page 5, first full paragraph.

The organic substances may be present alone or mixed with at least two substances. It is also expedient to formulate the substances to obtain forms which are simple to use, such as, for example, viscous oils, **pastes, gels, creams, suppositories or foams**, which can be distributed uniformly and completely on the surface of the entire birth canal. It is additionally possible with the formulation for the adhesion to

the surface of the birth canal to be improved and, where appropriate, additionally to the fetus skin to be reduced, so that an optimal duration and lubricant effect of the lubricant layer applied to the surface of the birth canal is achieved.

paragraph bridging pages 5 and 6.

Specific examples of organic substances as lubricants are: hydroxyethylcellulose, glycerol, polycarbophil, Carbopols (for example Carbopol 907, Carbomer 934P), hyaluronic acid and salts thereof, succinylated gelatin, liquid paraffin, white petrolatum, polyethylene glycols and polypropylene glycols and polyethylene/polypropylene copolymers (Pluronic 127), dimethicone, dimethiconol, cyclomethion, vegetable oils and fats, animal oils and fats, mineral oils and fats, surface-active substances (surfactants such as nonoxynol-9, phospholipids, pulmonary surfactants such as Lucinactant, Beractant, phospholipida e pulmone suis).

paragraph bridging pages 6 and 7.

Mention should also be made of polymers which form a lubricant film after application, for example hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinyl alcohol, polyethylene glycols, polypropylene glycols and ethylene oxide/propylene oxide copolymers.

page 7, first full paragraph.

Thus, it is clear that the specification provides that the composition contains organic substances and lubricant film-forming combination of water and "at least two substances." These at least two substances can be selected from the lists of ingredients, which recite a list of polyacrylic acids, e.g., "polycarbophil, Carbopols (for example Carbopol 907, Carbomer 934P)" and humectants, e.g., glycerol, hyaluronic acid, polyethylene glycols and polypropylene glycols and ethylene oxide/propylene oxide copolymers.

Nevertheless, without conceding the propriety of the Office Action rejection, and only in the interest of advancing prosecution, Applicant submits that claim 44 has been amended to recite in relevant part that the lubricant film-forming combination consisting

of water and at least two substances selected from the group consisting of hydroxyethylcellulose, glycerol, polycarbophil, carbopols, a polyacrylic acid, hyaluronic acid and salts thereof, succinylated gelatin, liquid paraffin, white petrolatum, polyethylene glycols, propylene glycol, polyethylene/polypropylene copolymers, dimethicone, dimethiconol, cyclomethion, vegetable oils, fats, animal oils, fats, mineral oils, fats, surface-active substances, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinyl alcohol, polyethylene glycols, polypropylene glycols, ethylene oxide, and propylene oxide copolymers. Written description support for this amendment can be found, inter alia, in the portions of the specification quoted above. No new matter has been added.

Applicant respectfully submits that claim 44 now even more fully satisfies the requirements of the first paragraph of 35 U.S.C. § 112. Accordingly, favorable reconsideration and withdrawal of this rejection are respectfully requested.

Response to Rejections under 35 U.S.C. § 103

Claims 28, 30, 32, 34, 37, 39, 41, and 42 remained rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller (U.S. 5,624,903) and Bringloe (U.S. 4,765,478). The Examiner provides counterarguments on pages 12-17 of the Office Action. Without conceding the propriety of these assertions, and only in the interest of advancing prosecution, Applicant submits that independent claim 28 has been amended to recite:

A method for reducing the frictional force between an item to be delivered and a birth canal surface of a mother in human vaginal child birthing so as to reduce injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of cesarean sections during birthing, which comprises the steps of:

- 1) applying an effective amount of an organic lubricant composition to cover said birth canal surface with the onset of labor; and
- 2) additionally applying an amount of said composition to said birth canal surface during labor wherein said additional amount is effective in keeping the birth canal surface covered with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered;

said composition comprising a lubricating organic substance comprising
a polyacrylic acid;

isotonicizing substances;

a humectant; and no alkali metal salts of metaphosphates;

wherein said composition is in the form of a paste, gel, cream, suppository, or foam, and wherein said composition has lubricant film-forming properties that effect said reduction of injuries to the mother's birth canal, reduced risk of episiotomy, reduced risk of vaginal interventions, and reduced risk of cesarean sections during birthing upon application to the mother's birth canal according to steps 1 and 2.

Written description support for the amendments can be found throughout the specification including, *inter alia*, the paragraph bridging pages 3 and 4 and on page 10.

No new matter has been added.

The Examiner asserted that in order to establish long-felt need, it is necessary to present objective evidence that an art-recognized problem existed for a long period of time without solution. In addition to the previously submitted evidence, Applicant submits herewith further objective evidence of an art-recognized problem existed for a long period of time without solution and have amended independent claim 28 to be commensurate in scope therewith.

First, Applicant submits that the Stamp et al. article (British Medical Journal, 2001), which is of record in this case (submitted on October 31, 2006), describes the long-felt problem of perineal trauma during and after childbirth as a long-felt and unmet problem. See page 1277, "Introduction." For this long-felt and unmet need, Stamp et al. reference articles by 1. Johanson, *Lancet*, 2000, 2. Klein, *Am. J. Obstet. Gynecol.*, 1994, 3. Myles, "A textbook for midwives," 1953, 4. Sleep, "Physiology and management of the second stage of labour" in Myles textbook for midwives, 1993, 5. Kitzinger and Simpkin in "Episiotomy and the second stage of labour, 1994. Further, on page 1277, in the paragraph bridging the left and right columns, Stamp et al. pointed to three other clinical trials (references 8-10 in Stamp et al.) aimed at reducing perineal tears during birthing that all failed to arrive at a significant reduction. Stamp et al. conducted a randomized controlled clinical study to determine if this need could be satisfied with perineal massage using a water-soluble lubricant produced by Johnson and Johnson (most likely KY-Jelly). Upon conclusion of the study, the authors concluded that "[t]he practice of perineal massage in labour **does not** increase the likelihood of an intact perineum or reduce the risk of pain, dyspareunia, or urinary and faecal problems." Abstract (emphasis added). Thus, Stamp et al. recognized the long-

felt unmet need of having to reduce the frictional force to prevent tearing during birth, but could not solve it through perineal massage.

Second, a 1996 article by Albers et al. (Journal of Nurse-Midwifery, 269-276) explains that “perineal trauma at childbirth is a common occurrence” and that 50% of vaginal births in the United States are “**still** accompanied by episiotomy.” Page 269, 1st paragraph (emphasis added). Further, Albers et al. note that spontaneous perineal laceration rates are approximately 40%. The article explains the impacts of perineal trauma on mothers. The authors studied whether nurse-midwifery practices increased the likelihood of an intact perineum following childbirth. It was found that the use of oils or lubricants did not increase the likelihood of an intact perineum following childbirth. In fact, the study reported that significantly more mothers did not have an intact perineum following childbirth when oils/lubricants were used. See Table 5 on page 274. Accordingly, Albers et al. is another example that the art had recognized the long-felt and unmet need to reduce injuries to the mother's birth canal and risk of episiotomy, but had been unable to satisfy the need. Moreover, Albers et al. demonstrates that the art had recognized that lubricant methods were ineffective for reducing perineal tears and episiotomies.

Third, Applicant submits herewith an article by Albers et al. (J Midwifery Womens Health), which was published in 2005. This follow-up article again states that “[g]enital tract trauma following spontaneous vaginal childbirth is common, and evidence-based prevention measures have not been identified, beyond minimizing the use of episiotomy.” Abstract. Three potential solutions to this long-felt, unmet need were assessed: 1) warm compresses to the perineal area, 2) massage with lubricant, and 3) no touching of the perineum until crowning of the infant's head. Upon conclusion of the

study, the authors concluded that “[n]either the use of warm compresses or perineal massage with lubricant late in the second stage of labor increased or decreased the overall rates of genital tract trauma” compared with no touching of the perineum until crowning. (page 8, final paragraph). Thus, Albers also recognized a need for reducing friction to reduce genital tract trauma and perineal tears, but could not meet the need. This need was clearly long-felt as Albers et al. published this article almost a decade after their previous article.

As evidence that the presently claimed composition satisfies the art-recognized need, Applicant submits herewith an article (Schaub, J. Perinat. Med. 2008), demonstrating that the claimed method and composition significantly increased perineal integrity in a clinical trial, thereby satisfying the long-felt need identified by Stamp et al. and Albers et al. See Table 5 on page 133 and paragraph bridging right and left columns on page 133 (“the rate of intact perineum increased by 15% with the obstetric gel use. This difference was statistically significant ($P=0.024$, Table 5).”

Further, submitted herewith is a Scientific Expert Report regarding the use of the inventive composition (referred to by its trademark Dianata) in several European studies. As can be derived from the Scientific Expert Report, the use of Dianatal® in human child birthing significantly reduces perineal tear rates, see Swiss study on pages 5-6 of the Scientific Expert Report and Slovenian studies, significantly reduces vaginal tear rates, see Slovenian retrospective comparative studies, reduces episiotomy rates, see Ukrainian study and Slovenian studies, vaginal operative procedure/intervention rates, see German study and Slovenian prospective study, and emergency cesarean rates, see German study and Slovenian prospective study.

Specifically, the results of the Swiss study, which were presented at the Annual Conference of the German Society of Gynecology and Obstetrics in Hamburg, September 2008, demonstrated that by using the claimed method, the risk of perineal tears was significantly reduced by two-fold. See page 5 of the Scientific Expert Report. Further, at two Ukrainian maternity hospitals, it was found that use of Dianatal® significantly reduced episiotomy rates from 28% without use of Dianatal® to 3% when Dianatal® is used in human child birthing. See page 6 of the Scientific Expert Report. Further, the German study has thus far demonstrated a reduction in vaginal operative rate of 34% and a reduction in emergency cesarean rate of 19%. See page 9 of the Scientific Expert Report.

Accordingly, it is clear in view of the above that a long-felt, unmet need existed to reduce one or more of injuries to the mother's birth canal, the risk of episiotomy, the risk of vaginal interventions, and the risk of cesarean sections during birthing. The presently claimed method has been shown to satisfy these needs.

Further, M.P.E.P. § 2141.02(V) provides that "it is [the] invention *as a whole*, and not some part of it, which must be obvious under 35 U.S.C. § 103." (quoting *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) (emphasis in original) (citations omitted)). Rejections made on grounds of obviousness cannot be based on what was not known at the time the invention was made, and consequently were not known to the person of skill. See M.P.E.P. § 2141.02(v). To do so is to rely on hindsight. It is the combination of elements as claimed which should be examined for and shown to be obvious before a patent claim is rejected. Here, Applicants submit that no combination of the cited references suggests the combination of features recited in the method of claim 28 when it is considered as a whole.

In view of the foregoing, Applicant respectfully submits that the independent claim 28 patentably defines the present invention over the citations of record. Further, the dependent claims should also be allowable for the same reasons as their respective base claims and further due to the additional features that they recite.

Claim 29 remained rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of JP 46-24256 ("JP '256"). The Examiner maintained that the combination of cited references and general knowledge discloses that the method is effective in humans and the step of applying additional amounts and that JP '256 is only cited for the amount of polyacrylic acid. Without conceding the propriety of these assertions, Applicant submits that the amendments and arguments to independent claim 28 patentably define over the combination of Kasahara, Van Leuven, Muller, and Bringloe. As JP 46-24256 is acknowledged to only be cited for the amount of polyacrylic acid, Applicant submits that JP 46-24256 does not remedy the deficiencies of the cited combination with regard to independent claim 28. Accordingly, Applicant respectfully submits that because independent claim 28 is believed to be allowable over the combination of cited art, claim 29 depending therefrom is also distinguished over the combination of cited art for at least the same reasons.

Claim 31 remained rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Behl et al. (U.S. 5,580,574). The Examiner asserted that Behl teaches that the purpose of CMC in its compositions is to obtain the desired consistency of the gel, not to facilitate or enhance transdermal penetration. Without conceding the propriety of these assertions, Applicant submits that the amendments and arguments to independent claim 28 patentably define over the combination of Kasahara, Van Leuven, Muller, and Bringloe. As Behl does not remedy the deficiencies of the cited combination with regard to independent claim 28, Applicant

respectfully submits that claim 31 depending from claim 28 is also distinguished over the combination of cited art for at least the same reasons.

Claims 35-36 remained rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Kasahara '797 (U.S. Patent 3,814,797). The Examiner stated that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Without conceding the propriety of the previously made assertions with regard to claims 35 and 36, Applicant submits that the amendments and arguments to independent claim 28 patentably define over the combination of Kasahara, Van Leuven, Muller, and Bringloe. As Kasahara '797 does not remedy the deficiencies of the cited combination with regard to independent claim 28, Applicant respectfully submits that claims 35-36 depending from claim 28 are also distinguished over the combination of cited art for at least the same reasons.

Claim 43 remained rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Dettmar (U.S. Patent 4,652,446). The Examiner stated that no new arguments were provided, thus these claims remain obvious because of the maintained rejection of independent claim 28. Without conceding the propriety of the previously made assertions with regard to claim 43, Applicant submits that the amendments and arguments to independent claim 28 patentably define over the combination of Kasahara, Van Leuven, Muller, and Bringloe.

As Dettmar does not remedy the deficiencies of the cited combination with regard to independent claim 28, Applicant respectfully submits that claim 43 depending from claim 28 is also distinguished over the combination of cited art for at least the same reasons.

Claim 33 was rejected under 35 U.S.C. § 103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Van Leuven (U.S. 4,267,168) as evidenced by Muller and Bringloe and further in view of Roder et al. (U.S. 6,217,885). The Examiner acknowledged that Kasahara, Van Leuven, Muller and Bringloe do not disclose the addition of carob flour, but asserts that Roder discloses cosmetic and/or pharmaceutical composition for use on human or animal skin which may be in the form of gels, creams, or foams, preferably 0.1 to 2% of thickeners and gelling agents, which include cellulose derivatives, alginates, and carob bean flour (col. 6, lines 38-42). Thus, the Examiner asserted that it would have been obvious to use carob flour as a thickener in the combined composition of the prior art because carob flour was a known thickener. Without conceding the propriety of these assertions, Applicant submits that the amendments and arguments to independent claim 28 patentably define over the combination of Kasahara, Van Leuven, Muller, and Bringloe. As Roder does not remedy the deficiencies of the cited combination with regard to independent claim 28, Applicant respectfully submits that claim 33 depending from claim 28 is also distinguished over the combination of cited art for at least the same reasons.

Claim 44 was rejected under 35 U.S.C. § 103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of JP 46-24256 (JP '256). The Examiner asserted that Van Leuven discloses a lubricant composition consisting of glycerine and that JP '256 discloses a lubricant composition consisting of sodium polyacrylate diluted to 0.2-0.3% in water. Accordingly, the Examiner asserted that it would have been obvious to combine the compositions with a reasonable expectation of success. With regard to the method steps, the Examiner asserted that it would have been obvious to apply the same composition in multiple steps because this a design choice within the purview of the skilled artisan. Applicant respectfully disagrees and traverses the rejection.

Applicant submits that Van Leuven's composition obligatorily includes a number of compounds outside the scope of claim 44 that significantly influence the lubricating effect of Van Leuven's composition, such as, for example, dodecyl benzene sulfonic acid and propylene glycol. Van Leuven does not disclose that the lubricant consists of glycerine as has been asserted in the subject Office Action. Rather, Van Leuven discloses a list of ingredients and discloses that sulfonic acid is essential to the lubricity and viscosity of the composition. Specifically, Van Leuven states:

The viscosity of the final composition is affected by the sulfonic acid or its salt. If the concentration is in excess of about 6% there appears to be some protective effect and the biocidal activity of the composition may be reduced. **If the concentration of the sulfonic acid or its salt is less than about 2.5% there may be insufficient cleaning action if the composition is used as a presurgery scrub and insufficient lubricity for use as a vaginal douche or delivery lubricant.** This range of composition in combination with the other ingredients also assures proper viscosity.

Col. 5, lines 5-15 of Van Leuven. (emphasis added)

It is clear that dodecyl benzene sulfonic acid is essential to the lubricating effect of Van Leuven. A person of ordinary skill in the art at the time of the invention could not

have arrived at the method of claim 44 after reading Van Leuven because it would have been clear that Van Leuven requires at least sulfonic acid to make the composition. JP '256 does not and cannot remedy this deficiency. JP '256 is an aqueous solution, which would not form a lubricant film, according to standard practice for use in animal deliveries, and therefore, no combination of Van Leuven and JP '256 renders obvious the method of claim 44.

In any case, claim 44, as amended, requires applying and reapplying "a composition comprising a lubricant film-forming combination **consisting of** water and at least two substances selected from the group consisting of glycerol, polycarbophil, carbopols, polyacrylic acid, hyaluronic acid and salts thereof, succinylated gelatin, liquid paraffin, white petrolatum, dimethicone, dimethiconol, cyclomethion, vegetable oils, vegetable fats, animal oils, animal fats, mineral oils, mineral fats, surface-active substances, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinyl alcohol, polyethylene glycols, polypropylene glycols, ethylene oxide copolymers, and propylene oxide copolymers; and no alkali metal salts of metaphosphates, wherein said composition is free of alkali metal salts of metaphosphates and in the form of a paste, gel, cream, suppository, or foam." The cited combination of Van Leuven and JP '256 do not suggest a composition having the claimed features.

In view of the foregoing, Applicant respectfully submits that claim 44 patentably defines the present invention over the citations of record. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

New Claims

Independent claim 45 has been added to define further embodiments of the invention. Written description support for this claim can be found throughout the application, including, *inter alia*, the paragraph bridging pages 3 and 4, on page 9, third and fourth paragraphs, and on page 10. No new matter has been added.

New claims 46 and 47 have been added to define further embodiments of the invention. Claim 46 excludes alginate from the lubricant organic substance of claim 28. Claim 47 excludes alginate from the composition of claim 28. The specification discloses alginate on page 2, 4th paragraph and page 6, 4th paragraph. Accordingly, the claim amendments do not present any issues of new matter because Applicant is only claiming, in these claims, less than Applicant has a right to claim. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."); see also M.P.E.P. § 2173.05(i) citing *In re Johnson* ("If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims."). Because alginic acid, which is synonymous with alginate (both CAS No. 9005-32-7), is essential to the composition of Kasahara, Applicant submits that new claims 46 and 47 are distinguished over the combination of cited references for at least this additional reason.

Conclusion

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

A Notice of Allowance is respectfully requested.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

By /Robert B. Murray/
Robert B. Murray
Attorney for Applicant
Registration No. 22,980
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040

RBM/AHH
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